IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BUZZFEED INC.,
111 East 18th Street, 13th Floor
New York, NY 10003

Plaintiff,

v.

Case No. 1:19-cv-01410

FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue
Silver Spring, MD 20993

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Ave., SW
Washington, DC 20201

U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
CDR, USAMRMC
810 Schreider Street
Fort Detrick, MD 21702-5000

U.S. DEPARTMENT OF DEFENSE
1400 Defense Pentagon
Washington, DC 20301-1400

Defendants.

COMPLAINT

1. Plaintiff BUZZFEED INC. files this Freedom of Information Act suit to force Defendants FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. DEPARTMENT OF DEFENSE, and U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND to release records related to the opioid drug Dsuvia made by the company AcelRX Pharmaceuticals ("AcelRX").

PARTIES

2. Plaintiff BUZZFEED INC. is a member of the media and made the FOIA requests at issue in this case.

3. Defendant U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ("DHHS") is a federal agency subject to the Freedom of Information Act, 5 U.S.C. § 552.

4. Defendant FOOD AND DRUG ADMINISTRATION ("FDA") is a federal agency and component of DHHS and is subject to the Freedom of Information Act, 5 U.S.C. § 552.

5. Defendant U.S. DEPARTMENT OF DEFENSE ("DOD") is a federal agency subject to the Freedom of Information Act, 5 U.S.C. § 552.

6. Defendant U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND ("USAMRMC") is a federal agency and component of DOD and is subject to the Freedom of Information Act, 5 U.S.C. § 552.

JURISDICTION AND VENUE

7. This case is brought under 5 U.S.C. § 552(a)(6)(c)(i) and presents a federal question conferring jurisdiction on this Court.

8. Venue is proper under 5 U.S.C. § 552(a)(4)(B).

DEFENDANTS' FOIA VIOLATIONS (FDA)

9. On February 28, 2019, BUZZFEED requested from FDA "[t]he following documents related to NDA 209128, submitted by AcelRX, seeking approval of Dsuvia (sufentanil): [1] All protocol amendments and related documents and communications between FDA and AcelRX or a representative of AcelRX regarding study SAP301 (registered on ClinicalTrials.gov as NCT02356588). [2] The report, along with all supporting documentation, referenced on page 6 of the Clinical Inspection Summary dated August 31, 2017, under the

heading '5. CRO' that begins 'This inspection was performed by European Medicines Agency (EMA) as a routine data audit' (on page 88 of the PDF available online [https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/209128Orig1s000OtherR.pdf])." A true and correct copy of the request is attached as Exhibit A.

10. On March 8, 2019, BUZZFEED requested from FDA "[a]ll communications between FDA and any member of Congress or the employees or representatives of any member of Congress that mention the drug Dsuvia, its generic name (sufentanil), other nicknames (such as 'SST,' 'SSTS,' 'NanoTab' or 'ARX-04') or the company AcelRX. All communications between any Department of Defense officials and FDA that mention Dsuvia, its generic name (sufentanil), other nicknames (such as 'SST,' 'SSTS,' 'NanoTab' or 'ARX-04'), or the company AcelRX." A true and correct copy of the request is attached as Exhibit B.

11. On March 14, 2019, BUZZFEED requested from FDA "[t]he following documents related to NDA 209128, submitted by AcelRX, seeking approval of Dsuvia (sufentanil): [1] All documents that relate to, describe, summarize or memorialize any communication from the FDA to any members of the Drug Safety and Risk Management Advisory Committee disinviting them from the October 12, 2018 Anesthetic and Analgesic Drug Products Advisory Committee meeting concerning Dsuvia. [2] All documents concerning the FDA's decision to disinvite members of the Drug Safety and Risk Management Advisory Committee from the October 12, 2018 Anesthetic and Analgesic Drug Products Advisory Committee meeting concerning Dsuvia. [3] All documents concerning the FDA's decision not to empanel the full Drug Safety and Risk Management Advisory Committee for consideration of the Dsuvia application." A true and correct copy of the request is attached as Exhibit C. A true and correct copy of FDA's automatic reply is attached as Exhibit D.

12. On April 5, 2019, FDA anticipated that it would take "at least 24 months" to comply with all of the requests. A true and correct copy of FDA's email is attached as Exhibit E.

13. As of the date this suit was filed, FDA has not provided any further responses or produced any records in response to the requests.

DEFENDANTS' FOIA VIOLATION (DOD)

14. On March 8, 2019, BUZZFEED requested from DOD "[a]ll communications between any Office of the Secretary of Defense and Joint Staff officials and any Food and Drug Administration officials that mention Dsuvia, its generic name (sufentanil), other nicknames (such as 'SST,' 'SSTS,' 'NanoTab' or 'ARX-04'), or the company AcelRX." A true and correct copy of the request is attached as Exhibit F.

15. On April 2, 2019, DOD sent a letter to BUZZFEED stating that it would not be able to comply with the request within the 20 business day statutory deadline and that there are approximately 2,900 FOIA requests in line before BUZZFEED's request. A true and correct copy of DOD's letter is attached as Exhibit G.

16. As of the date this suit was filed, DOD has not provided any further response or produced any records in response to the request.

DEFENDANTS' FOIA VIOLATION (USAMRMC)

17. On March 13, 2019, BUZZFEED requested from USAMRMC "[1] All documents and communications related to USAMRMC's evaluation of or provision of funding or other support for the drug eventually known as Dsuvia, an oral painkiller for battlefield analgesia (also known by names including, but not limited to, oral sufentanil, sublingual sufentanil, sufentanil, and SSTS). These records could be produced by, but are not limited to, the Combat Casualty Care Research Program and the Clinical and Rehabilitative Medicine Research

Program. [2] All communications between USAMRMC and any employee or representative of the pharmaceutical company AcelRX (including but not limited to email addresses ending in '@acelrx.com')." A true and correct copy of the request is attached as Exhibit H.

18. On April 19, 2019, USAMRMC acknowledged receipt of the request. A true and correct copy of USAMRMC's letter is attached as Exhibit I.

19. As of the date this suit was filed, USAMRMC has not provided any further response or produced any records in response to the request.

COUNT I – VIOLATION OF FOIA –FEBRUARY 28, 2019 REQUEST (FDA)

20. The above paragraphs are incorporated herein.

21. Defendants are agencies subject to FOIA.

22. Plaintiff made a FOIA request to Defendants for agency records of Defendants.

23. Defendants have failed to provide a determination with regard to the request.

24. Defendants have failed to produce the requested records promptly.

COUNT II – VIOLATION OF FOIA –FIRST MARCH 8, 2019 REQUEST (FDA)

25. The above paragraphs are incorporated herein.

26. Defendants are agencies subject to FOIA.

27. Plaintiff made a FOIA request to Defendants for agency records of Defendants.

28. Defendants have failed to provide a determination with regard to the request.

29. Defendants have failed to produce the requested records promptly.

COUNT III - VIOLATION OF FOIA –MARCH 14, 2019 REQUEST (FDA)

30. The above paragraphs are incorporated herein.

31. Defendants are agencies subject to FOIA.

32. Plaintiff made a FOIA request to Defendants for agency records of Defendants.

33. Defendants have failed to provide a determination with regard to the request.

34. Defendants have failed to produce the requested records promptly.

COUNT IV - VIOLATION OF FOIA – SECOND MARCH 8, 2019 REQUEST (DOD)

35. The above paragraphs are incorporated herein.

36. Defendants are agencies subject to FOIA.

37. Plaintiff made a FOIA request to Defendants for agency records of Defendants.

38. Defendants have failed to provide a determination with regard to the request.

39. Defendants have failed to produce the requested records promptly.

COUNT V - VIOLATION OF FOIA –MARCH 13, 2019 REQUEST (USAMRMC)

40. The above paragraphs are incorporated herein.

41. Defendants are agencies subject to FOIA.

42. Plaintiff made a FOIA request to Defendants for agency records of Defendants.

43. Defendants have failed to provide a determination with regard to the request.

44. Defendants have failed to produce the requested records promptly.

WHEREFORE, Plaintiff asks the Court to:

i. Order Defendants to conduct a reasonable search for records and to produce all non-exempt requested records;

ii. Award Plaintiff attorney fees and costs; and

iii. Enter any other relief the Court deems appropriate.

DATED: May 15, 2019

Respectfully Submitted,

/s/ Matthew Topic

Attorneys for Plaintiff

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